Prevention. How much harm? How much benefit? 3. Physical, psychological and social harm

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Abstract • Résumé

Harm caused by preventive programs may be physical, psychological, social or, if informed consent has not been obtained, ethical. Adverse effects of preventive screening programs may occur at any of the three levels of the "screening cascade": the screening procedure itself, the investigation of abnormal results of screening tests or the treatment of detected abnormalities or diseases. The greatest harm occurs at the second and third levels. Examples of procedures that may cause physical harm are venipuncture, mammography, colonoscopy, breast biopsy, transrectal ultrasonography, prostate biopsy, weight-reducing and cholesterol-lowering diets and radical prostatectomy. The psychological and social harm of preventive programs involves anticipated discomfort or perception of adverse effects of preventive interventions, unpleasant interactions with health care workers, time required for preventive programs, excessive overall awareness of health, anxiety over the results of a screening test, implications of a positive screening test, consequences of being labelled as "sick" or "at risk," psychopathologic effects induced directly by preventive programs and, in the case of a false-negative test result, false assurance of disease-free status. Since the positive predictive value of screening tests in the general population is always low, most abnormal test results are "false-positive;" these engender a great deal of psychological distress among patients.

Les préjudices causés par les programmes de prévention peuvent être de nature physique, psychologique ou sociale ou, si l'on n'a pas obtenu de consentement éclairé, éthique. Les programmes de dépistage préventif peuvent avoir des effets indésirables à l'un ou l'autre des trois niveaux de la «cascade du dépistage» : la procédure de dépistage même, l'analyse des résultats anormaux des tests de dépistage ou le traitement des anomalies ou des maladies détectées. Le préjudice le plus grave se produit aux deuxième et troisième niveaux. La ponction veineuse, la mammographie, la côlonoscopie, la biopsie du sein, l'ultrasonographie transrectale, la biopsie de la prostate, les régimes amaigrissants et hypocholestérolémiants et la prostatectomie radicale sont des exemples d'interventions qui peuvent causer des préjudices physiques. Les préjudices psychologiques et sociaux des programmes de prévention comportent l'inconfort anticipé ou la perception d'effets indésirables d'interventions préventives, des interactions désagréables avec des travailleurs de la santé, le temps nécessaire aux programmes de prévention, la sensibilisation globale excessive à la santé, l'anxiété suscitée par l'attente des résultats d'un test de dépistage, les répercussions d'un test de dépistage qui donne des résultats positifs, les conséquences d'être reconnu comme personne «malade» ou «à risque», les effets psychopathologiques provoqués directement par les programmes de prévention et, dans le cas de résultats d'analyse faussement négatifs, la fausse garantie d'absence de maladie. Comme la valeur prédictive positive des tests de dépistage dans la population générale est toujours faible, la plupart des résultats de tests anormaux sont «faussement positifs» et engendrent beaucoup de détresse psychologique chez les patients.

For patients and physicians to decide whether a specific patient should participate in a preventive program, they must know not only whether the program has proven benefits and how great these benefits are, but also whether there are associated adverse effects, how serious they are and how often they occur. The previous two articles in this series dealt with some of the pitfalls in determining the significance or even the presence of

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clinically significant benefits from reading the medical literature. This article reviews some of the ways in which preventive programs may cause harm, and the final article of the series will discuss clinical guidelines for prevention and the ethical norms of prevention.

The harm caused by prevention has received much less attention than its benefits. No one wants to hear bad news. Physicians may have already decided that the benefits outweigh any disadvantages, or they may be afraid that patients will not participate in preventive programs if they are aware of the potential harm. In many instances, detrimental effects are minimal, but that should not stop physicians or their patients from being aware of them.

The types of possible harm to patients participating in preventive programs may be classified as physical, psychological, social or, if informed consent has not been obtained, ethical. Many of these adverse sequelae occur during screening or case-finding programs and result from the "screening cascade," or the series of interventions involved in such programs.[1] The "screening cascade" consists of three levels: the screening process itself, the investigation of detected abnormalities and the management of identified disorders. Although adverse effects occur at all levels, the more serious ones are usually found at the second and third levels (Table 1).

Table 1: Potential harm at the three levels of the "screening cascade"

Level of screening cascade	Type of harm, examples
Screening process	**Physical**
	Discomfort resulting from venipuncture or breast compression during mammography
	Syncope resulting from venipuncture
	Psychological and social
	Anxiety over anticipated adverse effects of procedures and over test results
	Excessive awareness of health
Investigations of abnormal results	**Physical**
	Pain and complications of breast biopsy or colonoscopy
	Psychological and social
	Anxiety induced by positive results
	False reassurance from false-negative results
Treatment of detected abnormalities or diseases	**Physical**
	Adverse reactions to lipid-lowering drugs or hormone-replacement therapy
	Impotence, incontinence or death resulting from radical prostatectomy
	Psychological
	Distress resulting from actual or anticipated physical harm

A detrimental aspect of any preventive program is its cost to society;[2–8] the money spent on prevention is not available for other uses. The subject of such opportunity costs is an important one, but it is beyond the scope of this series. Instead, I will adopt the perspective of the physician and patient in an office setting, and I will deal with the balance of the benefits and harm of specific preventive programs for particular patients without considering the costs to society as a whole.

The fact that this article deals exclusively with the adverse effects of prevention does not imply that such programs should be eschewed; on the contrary, the harm-to-benefit ratio has to be weighed by physicians and patients, and specific decisions must be made for each program and each patient. This will be discussed further in the final article in this series.

Physical harm

Due to a screening process

At the first level of the screening cascade, mammography and venipuncture often cause minor discomfort. In one study, 35% of women stated that mammography caused physical discomfort and 6% described it as painful.[9] Complications of venipuncture are few and generally innocuous. In a study of 4050 venipunctures, minor bruising or hematoma resulted from 12.3% of procedures, diaphoresis with hypotension from 2.6% and syncope from less than 1%.[10] More serious sequelae of venipuncture include peripheral nerve injury and causalgia,[11] asystole,[12] anemia[13] and needle-stick injuries to those drawing the blood.[14]

Due to investigation of abnormal results

Three procedures often used in the investigation of abnormal results of screening tests are colonoscopy, breast biopsy and prostate biopsy.

Colonoscopy

Important physical adverse effects of colonoscopy are pain,[15] vasovagal reactions,[16] perforation, hemorrhage and death.[17,18] Reported rates of major complications after colonoscopy vary, but are typically 1 in 600 for perforation, 1 in 3600 for significant hemorrhage and 1 in 5000 for death.[17]

Breast biopsy

Biopsy of suspicious breast abnormalities detected by mammography is usually performed after needle localization of the lesion. Rappaport and associates[19] re-

ported 11 wound infections after 144 consecutive needle-localization biopsies; in another series of 301 biopsies, there were 12 hematomas, 3 abscesses, 1 seroma and 2 wound separations.[20] Vasovagal reactions have been reported in 7% and syncope in 1% of patients undergoing needle aspiration or localization of breast lesions.[21]

Prostate biopsy

If the result of screening for prostate cancer by either digital rectal examination or prostate-specific antigen testing is positive, the next step in the "screening cascade" is usually transrectal ultrasonography and needle biopsy of the prostate. A transrectal ultrasonographic examination appears to cause severe discomfort among only 5% of patients,[22] whereas the incidence of pain from needle biopsy has been reported to be 8%[22] and 31%.[23] Both hematuria and hemospermia occur among more than half of all patients who have a needle biopsy.[23,24] Infection rates vary from about 1% to 6% but are lower among patients given prophylactic antibiotics.[22,24] In a very few cases septicemia and even death have been reported.[25] Acute urinary retention is a rare complication.[23]

Due to treatment

The most serious harm resulting from preventive programs involves the treatment of detected abnormalities or diseases.

Weight-reducing and cholesterol-lowering diets

Weight-loss diets, whether self-prescribed or prescribed by health care professionals, are probably the most prevalent,[26–28] expensive and ineffective[28] preventive programs in our society. Weight loss is correlated with increased rates of death from all causes and from cardiovascular causes, even when calculations are controlled for existing diseases and cigarette smoking.[29–31] The incidence of cholelithiasis is increased among patients eating very low-energy diets,[32] although less stringent diets may not have this effect.[33] High-fibre, low-energy diets have been associated with lower bone density among postmenopausal women, compared with the bone density among control women who were not dieting.[34]

One of the more serious consequences of weight-loss diets is an increase in the incidence of eating disorders, which have numerous psychological and physical sequelae.[35–37] The adverse consequences of dieting may even be transmitted from one generation to the next. A group of mothers whose children failed to thrive as a result of food restriction scored much higher on a food-restraint scale than a comparable group of mothers whose children did not fail to thrive.[38] None of the mothers in either group met the criteria for having an eating disorder. This type of generational effect is also seen on a societal level. One study showed that 72% of US high school children had attempted to diet in the 1 to 2 months before the survey,[39] and another study found that even third-grade students had tried dieting.[40] Although the cultural importance of being thin is undoubtedly a major cause of such behaviour, medical recommendations probably also play a significant role.[41] For example, the consensus conference on lowering blood cholesterol levels, held by the US National Heart, Lung and Blood Institute, issued a statement that all Americans over 2 years of age should reduce their intake of dietary fat.[42] It has been suggested that such a reduced-fat diet may be insufficient for optimal growth and development in children,[41] although no adverse effects were documented in a 3-year trial involving children 8 to 11 years of age who were fed diets in which only 28% of energy was supplied from fat.[43]

Cholesterol-lowering drugs

Many drugs are used to lower cholesterol levels in order to prevent coronary artery disease, and each of these drugs has its own spectrum of adverse effects. As well, lowering cholesterol itself may be harmful. Two meta-analyses of controlled trials of cholesterol-lowering diets and drugs found that all of the groups undergoing treatment had a significantly higher rate of death from suicide, accidents and violence.[44,45] Other studies have shown a correlation between low cholesterol levels and overall death rates,[46,47] rates of death from injuries and suicide[48] and rates of attempted suicide.[49] There is also experimental evidence supporting this connection: one study showed that contact aggression was increased in monkeys fed cholesterol-lowering diets.[50] One explanation for this effect is that either low cholesterol levels or drugs that lower cholesterol levels tend to induce depression.[51,52] The issue is controversial because not all workers agree with these findings[53] and because one primary-prevention trial of pravastatin[54] and one secondary-prevention trial of simvastatin[55] showed no evidence of an increase in violence or suicides in the groups taking the drugs.

Radical prostatectomy

In the United States and Canada, the usual treatment for proven localized prostate cancer is radical prostatectomy. A survey of 2122 patients who underwent this procedure in 484 institutions in the United States in 1990 showed the following complications.[56] Of the patients, 0.7% died as a result of surgery, 56.6% of those

who were potent before surgery became impotent, 3.6% became completely incontinent, 4.1% required more than two pads daily for incontinence, 11.2% required two pads or less daily and 23.1% had occasional incontinence but did not use pads.[56]

Psychological and social harm

Adverse psychological, social or ethical consequences of preventive programs are listed in Table 2. This is an area of great importance but one in which much more research is needed.[57,58]

Anticipated discomfort or perception of adverse effects resulting from preventive interventions

Participants in screening programs may have realistic or exaggerated perceptions of the degree of discomfort the interventions will cause. Most people are a little discomfited by the thought of having a venipuncture; for a few, the idea of a needle puncture is truly terrifying.[59] Some women are embarrassed about exposing their breasts during mammography,[60] and a few fear that the radiation[60,61] or breast compression[62] involved in mammography will cause cancer.

Unpleasant interactions with health care workers

A screening program inevitably exposes the participants to increased contact with a variety of health care workers. If any of these workers is uncommunicative, curt or cold, the interaction is unpleasant for the participants.[61]

Time required for preventive programs

Preventive programs place demands on participants' time. An initial visit to a physician's office can take up to half a day when transportation and waiting time are factored in. More time is required if the patient is sent to a test centre for venipuncture or to a radiography facility for a mammogram. If a screening test has a positive result, many hours may be required to comply with further investigations and consultations. All of this is time lost from family commitments, work or play.

In countries such as Canada where the costs of most preventive screening programs are covered by public health insurance, the personal financial costs of screening are usually indirect and are limited to loss of income because of time lost from work. However, even in countries with universal coverage, the often substantial cost of drugs prescribed for prevention may not be covered.[63]

Table 2: Adverse psychological, social and ethical effects of preventive programs

Adverse effect	Examples
Anticipated discomfort or perceived adverse effects	Pain from needle puncture for blood tests Pain from breast compression during mammography Fear of radiation from mammography Unpleasantness of diet or exercise
Unpleasant interactions with health care workers	Unpleasantness of dealing with curt or uncommunicative personnel in a mammographic screening centre
Time required	Guilt or anxiety concerning time taken from work or family Decrease in functioning at work or at home
Personal financial costs	Loss of income because of time taken from work Payment for specific investigations or prescriptions
Excessive overall awareness of health	Change in perception of general health resulting from worry over elevated cholesterol level or risk of heart disease, stroke or cancer
Anxiety over the results of a screening test	Specific worry that the result of the screening test will be positive
Implications of a positive result of a screening test	Anxiety over the consequences of having a specific disease Decrease in social functioning because of anxiety and time required for further evaluation
Being labelled as "sick"or at "high risk" because of a positive result of a screening test	Dysthymia due to narcissistic injury Decrease in social functioning
Psychopathologic effects of preventive programs	Eating disorder caused by dieting
False assurance of disease-free status	False sense of security resulting from true-negative or false-negative test result
Failure to obtain informed consent	Loss of autonomy Lack of knowledge of possible adverse effects

Excessive overall awareness of health

In North America there is a great deal of concern about bodily functions and health.[2,64–67] Two decades ago, Thomas[64] described Americans as having an unhealthy obsession with health. If anything, the situation has worsened. Phrases such as the "tyranny of health"[66] and a "death-denying culture"[2] have been used to describe current attitudes.

Does participating or considering participating in a screening program add to the alarm people already feel about their health? In this area there are fewer data than hypotheses; however, there are reports that such interventions are psychologically stressful[58,59,68–71] and may lead to "cancerophobia"[68–70] and increased concern about heart disease.[71]

One could argue that the increased anxiety caused by screening programs is a positive outcome because it stimulates patients to look after their health. It may do so. However, assuming increased anxiety to be desirable is a value judgement in which greater worth is ascribed to preoccupation with and possible improvement in health than to comfortable denial or ignorance. Herein lies a paradox: the more attention and introspection we devote to health, the more we tend to amplify symptoms and to make a negative appraisal of our health.[67,72–74] In a nutshell, the more concerned we are about our health, the worse we feel.

Anxiety over the results of a screening test

An inevitable consequence of participating in a preventive program is a greater awareness and often a greater fear of the disease concerned. This concern is sometimes magnified because the anticipated results are perceived emotionally and in black-and-white terms: "Either my cholesterol level will be normal and I will not have to worry about heart attacks, or it will be elevated and I will suddenly drop dead. Either my mammogram will be normal and I will not have to worry about breast cancer, or it will not be and I will die an agonizing, horrible death." Shades of grey and risk spectrum are not part of most people's conception of illness.[58] For example, few nonphysicians understand the concept of precancerous conditions such as cervical intraepithelial neoplasia, and, as a result, they tend to view even a mildly abnormal result of a Papanicolaou smear as a diagnosis of cancer.[75]

Implications of a positive result of a screening test

A positive result of a screening test leads to a great deal of emotional distress.[57] In one study, about a quarter of the women who received a letter informing them that their Papanicolaou smear result was abnormal used phrases such as "stunned," "shocked" or "devastated" to describe their reactions.[75] Even being informed that the result of a screening test is false-positive does not always eliminate psychological distress.[58,76–79] Lerman and collaborators[78] studied the psychological status of a group of women who had received false-positive "high-suspicion" results of mammography. Although these women had known for 3 months that they did not have breast cancer, 47% were anxious about having further mammograms, 41% were worried that they had breast cancer and 17% reported a persistent decrease in their ability to engage in daily activities. Similar evidence of persistent anxiety among women with false-positive results of mammographic screening has also been reported by Gram and Slenker.[79]

Physicians and patients should realize that most positive results of any screening program conducted in the general population are false-positive; the positive predictive value is always low. For example, Mandel and colleagues[80] found that 97.8% of patients with positive results of stool tests for occult blood did not have colon cancer and that 70% had neither colon cancer nor adenomatous polyps. In a study conducted in Scotland involving 91 028 women screened by mammography, 6667 (7.3%) of the women were recalled for repeat mammography or other investigations and 578 (0.6%) were found to have cancer.[81] For 91.4% of the women who were recalled, the initial mammogram was a false-positive one. Although not all women who are recalled because of an abnormal mammogram find the experience psychologically traumatic, many do.[82]

Being labelled as "sick" or at "high risk"

One of the reported detrimental effects of a positive result of a screening test is that the patient is labelled as "sick." This labelling can cause psychological distress[83–87] and decreased occupational functioning.[87] Not all studies have documented this phenomenon.[88] It is thought that this is because more recent investigations have incorporated supportive patient counselling that has effectively counteracted the negative consequences of labelling.[88,89]

Being labelled as at high risk of a disease produces similar psychological effects. In one study, conducted during a 3-year period, a third of men who had been informed that they were at a high risk of having a heart attack suffered from intrusive thoughts and psychological distress.[90]

Psychopathologic effects induced directly by preventive programs

Patients who diet, and especially those who go through repeated cycles of dieting ("yo-yo dieting"), have been reported to experience a decrease in life satis-

faction and sexual drive, and an increase in fatigue, irritability and depression.[91,92] As I noted previously, one of the serious consequences of weight-loss diets is an increase in the incidence of eating disorders, which have psychological and physical sequelae.[35–37]

False assurance of disease-free status

A negative result of a screening test does not rule out the presence of disease. Such a result may cause a false sense of reassurance, which may, in turn, lead to neglect of other aspects of self-care.[93,94] True-negative results may also have this effect. For example, a smoker with a normal cholesterol level may feel justified in continuing smoking, or a postmenopausal woman may ignore minor vaginal bleeding because she had a normal result of a Papanicolaou smear.

Conclusion

Physicians must be as knowledgeable about the harmful effects of prevention as they are about its benefits; otherwise, they will be incapable of giving their patients a balanced perspective when they discuss the pros and cons of preventive interventions.

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